IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF VIRGINIA
Richmond Division

MONICA L. BALL,

Plaintiff,

v. Civil Action No. 3:13-cv-00168-JAG

TAKEDA PHARMACEUTICALS AMERICA, INC., *et al.*,

Defendants.

MEMORANDUM OPINION

In this prescription drug product liability case, the plaintiff, Monica Ball, alleges that she suffered infertility and contracted Stevens-Johnson syndrome as a result of taking Dexilant, a drug manufactured, marketed, and distributed by the defendants (collectively, "Takeda").

Nearly three years after sustaining her claimed injuries, and following repeated (and mostly unsuccessful) efforts to amend her claims against the defendants, Ball has not advanced her lawsuit beyond the initial pleadings stage. In the most recent Amended Complaint, Ball raises four causes of action against nine defendants: (1) negligence; (2) negligence *per se*; (3) breach of implied warranty; and (4) violation of the Virginia Consumer Protection Act ("VCPA"), Va. Code § 59.1-200 *et seq*. Seven of the nine defendants were only recently added as parties to the Amended Complaint. The defendants seek partial dismissal of Counts I and III, and complete dismissal of Counts II and IV.

The Court will dismiss the entire case. Ball's claims pertaining to Stevens-Johnson syndrome fail as a matter of law because Takeda disclosed the risk of developing this illness in Dexilant's packaging. The Court dismisses the plaintiff's negligent design and negligent manufacturing claims because Ball does not articulate the factual basis for these claims. Ball's

"failure to test" claim fails because Virginia law does not recognize this claim. The Court dismisses the negligence *per se* claim because plaintiff has not identified the specific law or regulation she believes the defendants violated. The VCPA claim fails as a matter of law because the Act does not apply to transactions in federally-regulated prescription drugs.

In addition, Ball faces another problem: she has not identified an expert witness as required by the Court's pretrial order. Without expert testimony, even if she could state viable products liability claims against the defendants, she could not prove her case. Ball seeks an extension of time to disclose an expert, but good cause does not exist for extending the deadline. Accordingly, the Court denies plaintiff's motion for an extension of the expert disclosure deadline and dismisses the entire case.

Various other motions relating to discovery and other matters are pending and will be denied.

I. MATERIAL FACTS

In addressing the motion to dismiss, the Court assumes Ball's well-pleaded allegations to be true, and views all facts in the light most favorable to her. *T.G. Slater & Son v. Donald P. & Patricia A. Brennan, LLC*, 385 F.3d 836, 841 (4th Cir. 2004).

Takeda manufactures and distributes Dexilant, a drug used to treat acid reflux disease and other gastrointestinal ailments.[1] In September 2010, Ball's doctor prescribed 60 milligrams of Dexilant to treat her gastric problems. Ball alleges that Dexilant caused her fallopian tubes to close, as well as the development of a condition known as "Stevens-Johnson Syndrome." Stevens-Johnson syndrome is a painful disorder that may cause the skin to die and shed.

[1] The Amended Complaint alleges that Takeda manufactures and distributes "Dexilant and Kapidex." (Am. Compl. ¶¶ 15, 27.) Apparently, Kapidex has been renamed Dexilant, (*id.*), so the Court refers to the drug at issue exclusively as Dexilant.

According to Ball, medical studies and scientific research have shown impaired fertility (including damage to the fallopian tubes) following the use of ingredients found in Dexilant. Ball contends that, even though Takeda knew or should have known of the potential injuries that could result from using Dexilant, the drug's packaging inserts lacked any information or warning of the drug's potential to cause fallopian tube closure or Stevens-Johnson syndrome.

Although the plaintiff refers repeatedly to the package insert in her complaint and arguments, the Court has experienced difficulties in pinning Ball's counsel down about the precise contents of the insert. Accordingly, the Court ordered Ball to produce the relevant package insert, but she has not done so. Takeda, however, has proffered the insert, and Ball agrees that the insert produced by Takeda is the one relevant to this case. Because she refers to it frequently in her case, the Court will consider the package insert in ruling on the motion to dismiss.

II. PROCEDURAL HISTORY

This case has an unnecessarily protracted history.

On September 28, 2012, Ball initially filed suit against Takeda Pharmaceuticals America, Inc., and Takeda Pharmaceutical, Ltd., in the Circuit Court of Henrico County, Virginia. *See Ball v. Takeda Pharms. Am., Inc.*, Case No. CL12-2755. On October 25, 2012, the defendants removed the matter to this Court. Case No. 3:12-cv-758-JAG ("*Takeda I*").

In *Takeda I*, the complaint alleged nine causes of action against the two defendants arising out of plaintiff's use of Dexilant. The defendants moved to dismiss the complaint, after which plaintiff twice unsuccessfully sought to amend her lawsuit. *See Takeda I* (dkt. nos. 20, 21, 23, 24, 26). The Court denied the plaintiff's motions to amend because each proposed amended

complaint failed to provide the defendants with fair notice of the facts and legal bases upon which liability rested. *See Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 555 (2007).

Ball's counsel refused to participate in the required Rule 26(f) conference, failed to propound initial disclosures in compliance with the Court's Initial Pretrial Order, became uncooperative with defense counsel, and generally resisted the orderly progression of the case. Counsel also ignored the Rules of Civil Procedure. On March 1, 2013, and without first seeking leave of Court, *see* Fed. R. Civ. P. 15(a)(2), Ball filed another proposed amended complaint. *Takeda I* (dkt. no. 33). Plaintiff did not seek leave to amend until nearly a week later on March 7, 2013. *Id.* (dkt. no. 34). Because the failure to follow the rules had become so egregious, the Court granted the defendants' motion for sanctions and dismissed the action without prejudice on March 15, 2013. *See id.* (dkt. no. 39).

That same day, Ball filed a new lawsuit in this Court against Takeda Pharmaceuticals America, Inc., and Takeda Pharmaceutical, Ltd. *See* Case No. 3:13-cv-168-JAG-MHL ("*Takeda II*"). *Takeda II* alleged eight causes of action against these two defendants arising out of plaintiff's use of Dexilant: (1) failure to warn; (2) "failure to provide precautions;" (3) breach of implied warranty; (4) breach of express warranty; (5) negligence; (6) "negligence regarding physician's standard of care concerning Stevens-Johnson Syndrome;" (7) fraud; and (8) punitive damages. Unfortunately, plaintiff's inability to comply with the rules persisted. Contemporaneous with the service of *Takeda II*, Ball also served written discovery on the defendants (including an excessive number of interrogatories) prior to the parties' Fed. R. Civ. P. 26(f) conference. Because this filing was improper, *see* Fed. R. Civ. P. 26(d)(1), the Court quashed the plaintiff's discovery requests and issued a Protective Order. *Takeda II* (dkt. no. 17).

The defendants moved to dismiss *Takeda II* for failure to state a claim, and Ball sought leave to amend her complaint. *Id.* (dkt. nos. 4 and 20). The Court denied Ball's motion to amend because a brief in support did not accompany her motion, *see* E.D. Va. Loc. Civ. R. 7(F), and because the sixty-three (63) page, 326-paragraph proposed amended complaint did not comply with Rule 8 of the Federal Rules of Civil Procedure. *Takeda II* (dkt. no. 22); *see also* April 26, 2013 Hr'g Tr. 24. The Court dismissed plaintiff's entire complaint without prejudice because the lawsuit contained numerous incomprehensible paragraphs and failed to offer a "short and plain statement of the claim showing that the pleader is entitled to relief." *Takeda II* (dkt. no. 22 (quoting Fed. R. Civ. P. 8(a)(2))). The Court dismissed *with prejudice* Count II (failure to provide precautions), Count VI (negligence regarding physician's standard of care), Count VII (fraud) and Count VIII (punitive damages). *Id.*

Plaintiff thereafter sought leave to file another amended Complaint, which the Court granted on May 9, 2013. *Id.* (dkt. no. 26). The current Amended Complaint, which is the subject of the defendants' motion to dismiss, levels four claims against Takeda: (1) negligence; (2) negligence *per se*; (3) breach of implied warranty; and (4) violation of the VCPA.

Although all of Ball's previous complaints and attempted amendments only named Takeda Pharmaceuticals America, Inc., and Takeda Pharmaceutical Company, Ltd., as defendants, the amended complaint, for the first time, seeks relief against not only these two Takeda entities but also seven others: Takeda Pharmaceuticals North America, Inc., Takeda Pharmaceuticals International, Inc., Takeda Pharmaceuticals, LLC, Takeda America Holdings,

Inc., Takeda Global Research & Development Center, Inc., Takeda San Diego, Inc. and TAP Pharmaceuticals Products, Inc.[2]

Takeda seeks dismissal of the newly-named defendants from the case, requests partial dismissal of Counts I and III, and seeks complete dismissal of Counts II and IV for failure to state a claim upon which relief can be granted. *Id.* (dkt. no. 30).

III. STANDARD OF REVIEW

A Rule 12(b)(6) motion to dismiss tests the sufficiency of a complaint; it does not resolve contests surrounding the facts of the case, the merits of a claim, or the applicability of any defense. *Republican Party of N.C. v. Martin*, 980 F.2d 943, 952 (4th Cir. 1992). In considering such a motion, the Court will accept all allegations in the Amended Complaint as true and will draw all reasonable inferences in favor of the plaintiff. *See Edwards v. City of Goldsboro,* 178 F.3d 231, 244 (4th Cir. 1999).

To survive the defendants' motion to dismiss, Ball must provide "more than labels and conclusions" because "a formulaic recitation of the elements of a cause of action will not do." *Bell Atl. Corp.*, 550 U.S. at 555 (citation omitted). Indeed, the legal framework of the Amended Complaint must be supported by factual allegations that "raise a right to relief above the speculative level." *Id.* "Threadbare recitals of the elements of a cause of action, supported by mere conclusory statements, do not suffice." *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009). "[O]nly a complaint that states a plausible claim for relief survives a motion to dismiss." *Id.* (citation omitted). The plausibility standard requires more than a showing of "a sheer possibility that a defendant has acted unlawfully." *Id.* In other words, "[a] claim has facial plausibility

[2] The Amended Complaint's caption names Takeda Pharmaceuticals America, Inc. twice as a defendant.

when the plaintiff pleads factual content that allows the court to draw the reasonable inference that the defendant is liable for the misconduct alleged." *Id.*

IV. DISCUSSION

A. The Court Dismisses All Claims Against the Seven New Takeda Defendants.

Ball's claims against the new Takeda defendants must be dismissed. The Amended Complaint does not plead sufficient facts to create a plausible inference that the new defendants are liable for the misconduct the plaintiff alleges.[3]

Ball merely says that Takeda Pharmaceutical Company, Ltd. "is the parent/holding company of," and "exercises dominion and control over," five of the newly named defendants. (Am. Compl. ¶¶ 6-7.) Under corporate law, however, the legal rights of parent and subsidiary corporations are separate. *See United States v. Bestfoods, Inc.*, 524 U.S. 51, 61 (1998); *Broussard v. Meineke Disc. Muffler Shops*, 155 F.3d 331, 349-50 (4th Cir. 1998). Thus, although many of the newly named defendants may be subsidiaries of Takeda Pharmaceutical Company, Ltd., such an allegation does not provide a sufficient factual basis for their inclusion in this lawsuit. *See, e.g., Mack v. AmerisourceBergen Drug Corp.*, 2009 U.S. Dist. LEXIS 109705, at *26 (D. Md. Nov. 24, 2009) (dismissing products liability lawsuit against Johnson & Johnson because "Plaintiffs have provided no justification for disregarding the parent/subsidiary distinction, as they cannot show that the corporate form was being misused for some improper purpose."), *aff'd*, 432 F. App'x 201 (4th Cir. Apr. 26, 2011).

[3] The defendants argue—probably correctly—that the claims against the new defendants are barred by Virginia's two-year statute of limitations. Va. Code § 8.01-243(A). Ball argues that her claim relates back to the filing to *Takeda I* under F.R.C.P. 15(c), but she has made none of the required showings for relation back under Rule 15(c)(1)(C). Because the Court dismisses the claims on other grounds, it need not address the issues involving the statute of limitations.

The Amended Complaint fares no better with respect to the defendants not included under the Takeda Pharmaceutical Company, Ltd., corporate umbrella. Newly named defendant Takeda America Holdings, Inc. is simply alleged to be a New York corporation with its principal place of business in New York City, while Defendant TAP Pharmaceuticals Products, Inc. ("TAP") is believed to be "directed and controlled by" one of the eight other Takeda defendants. (Am. Compl. ¶¶ 9, 12-13.)

Moreover, the plaintiff does not allege that the seven new defendants played any role in the manufacture, design, testing, marketing, labeling, or distribution of Dexilant.[4] Absent such allegations, the Court dismisses all claims against the new defendants, with prejudice.

B. Takeda Disclosed Stevens-Johnson Syndrome as a Reaction to the Use of Dexilant.

Ball alleges that Dexilant caused her to develop Stevens-Johnson syndrome. With respect to her claims of negligence and negligence *per se*, Ball contends that Dexilant's label did not include a warning of the potential risk for developing Stevens-Johnson syndrome. (Am. Compl. ¶¶ 21, 32, 40, 44.) Takeda seeks dismissal of Counts I and II, in part, on the basis that Dexilant's labeling did, in fact, identify Stevens-Johnson syndrome as a possible side effect.[5]

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[4] Ball pleads all of her allegations against "Takeda" generally, and no attempt is made to differentiate or clearly identify which of the nine defendants played a particular role in the manufacture or sale of Dexilant or in relation to the plaintiff's sustained injuries. While there exists no "bright-line prohibition" on such pleading, "courts have at times struggled with allegations drafted in this manner," requiring a reviewing court to "parse each claim to determine whether the undifferentiated allegations, if true, plausibly state a claim." *Alliance Tech. Group, LLC v. Achieve 1, LLC*, 2013 U.S. Dist. LEXIS 4708, at *11 (E.D. Va. Jan. 11, 2013). In the Amended Complaint now under review, many of the omnibus allegations against "Takeda" are conclusory, meriting minimal credit. *Iqbal,* 556 U.S. at 678. Indeed, "[a] plaintiff must identify, with particularity, each individual defendant's culpable conduct; defendants cannot be grouped together without specification of which defendant committed which wrong." *Arnlund v. Smith*, 210 F. Supp. 2d 755, 760 (E.D. Va. 2002) (internal quotations omitted).

[5] Takeda also seeks partial dismissal of Count III, breach of implied warranty, to the extent it seeks to hold the defendants liable for Ball's Stevens-Johnson syndrome. However, Count III

Although, as a general rule, extrinsic evidence should not be considered at the 12(b)(6) stage, "when a defendant attaches a document to its motion to dismiss, a court may consider it in determining whether to dismiss the complaint if it was integral to and explicitly relied on in the complaint and if the plaintiffs do not challenge its authenticity." *Am. Chiropractic Ass'n v. Trigon Healthcare, Inc.*, 367 F.3d 212, 234 (4th Cir. 2004) (citations omitted); *see also Tellabs, Inc. v. Makor Issues & Rights, Ltd.*, 551 U.S. 308, 322 (2007). Here, the Court considers the relevant Dexilant label because Ball referred to and relied upon it in her Amended Complaint, and because she has conceded it is genuine. (*See* Am. Compl. ¶ 44 ("Stevens-Johnson Syndrome was not listed in the warnings and precautions in 2010"); *see also* Apr. 26, 2013 Hr'g Tr. 29-30.)

The March, 2010 Dexilant label clearly identifies Stevens-Johnsons syndrome as a potential "adverse reaction" that could result from use of the prescription drug. (*See* Defs.' Mem. Supp. Mot. Dismiss, Ex. 1-A at 3 (dkt. no. 31-1).) Under Virginia law, a manufacturer is obligated "to give a reasonable warning, not the best possible one." *Pfizer, Inc. v. Jones*, 272 S.E.2d 43, 45 (Va. 1980) (citation omitted). Courts have routinely held warnings adequate as a matter of law when they alert a party to the very injury for which the plaintiff seeks relief. *See id.* (finding the warning adequate as a matter of law where the prescribing physician was warned of the risk, but was not told exactly how the danger would operate); *Kling v. Key Pharmaceuticals, Inc.*, No. 93-1827, 1994 U.S. App. LEXIS 24115, at *6 (4th Cir. Sept. 6, 1994) (applying Virginia law) (warning reasonable as a matter of law because "[t]he precise harm alleged to be suffered by Kling, a seizure, was clearly listed as a potential side effect of taking Theo-Dur."); *Barnette v. E.R. Squibb & Sons, Inc.*, 670 F. Supp. 650, 651 (E.D. Va. 1987) (granting judgment as a matter of law where both the Physician's Desk Reference and package

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only refers to damage to Ball's reproductive system. Count III does not seek to tie Takeda's supposed breach of warranty to Ball's Stevens-Johnson syndrome.

inserts carried warnings that the harm plaintiff suffered was a possible side effect associated with the use of the drug, even where the plaintiff argued, but failed to show, that the physician may not have received the packaged insert); *Ehlis v. Shire Richwood, Inc.*, 367 F.3d 1013 (8th Cir. 2004) (finding for the defendant where the warning section of the label clearly indicated that the drug could cause psychosis at recommended doses).

Takeda disclosed Stevens-Johnson syndrome as a possible adverse reaction to Dexilant prior to plaintiff's ingesting the drug in September, 2010. The failure to disclose this risk is the *sine qua non* of the plaintiff's negligence and negligence *per se* claims to the extent they seek to hold Takeda responsible for plaintiff's Stevens-Johnson syndrome. Those claims are dismissed, with prejudice.

C. Negligent Design and Negligent Manufacturing.

Takeda also seeks partial dismissal of plaintiff's claims to the extent she attempts to assert causes of action for negligent design or negligent manufacturing. In Counts I and II, Ball contends that Takeda was negligent "in the formation or manufacture of Dexilant" by failing to: adequately warn about the product's adverse effects, properly instruct consumers regarding Dexilant's use, and adequately test the product "before placing it in use." (Am. Compl. ¶¶ 22, 41.) She also argues that Takeda sold Dexilant "in a defective condition," causing her injuries. (*Id.* ¶ 40.) In Count III (breach of the implied warranty), plaintiff suggests that Takeda's manufacture and design of the product was negligent when it "injected into the stream of commerce" a drug "in a defective, unsafe, and inherently dangerous condition." (*Id.* ¶¶ 47-55.)

A manufacturer does not insure its product's safety, *Owens-Corning Fiberglas Corp. v. Watson*, 413 S.E.2d 630, 634 (Va. 1992), and need not "supply an accident-proof product." *Besser Company v. Hansen*, 415 S.E.2d 138, 144 (Va. 1992). To recover under a claim of

negligent manufacturing, negligent design or breach of warranty, a products liability plaintiff must show that (1) the drug was unreasonably dangerous for the use to which it would ordinarily be put or for some other reasonably foreseeable purpose, (2) the unreasonably dangerous condition existed when the drug left the defendant's hands, and that (3) the defect resulted from the defendant's failure to exercise "due care" in the manufacturing process. *Chestnut v. Ford Motor Co.*, 445 F.2d 967, 968-69 (4th Cir. 1971); *Logan v. Montgomery Ward & Co.*, 219 S.E.2d 685, 687 (Va. 1975).

The amended complaint does little more than provide a formulaic recitation of the elements of the plaintiff's manufacturing and design defect claims. Ball fails to allege any facts that would permit the Court to conclude that a manufacturing or design defect existed, or that such a defect was the proximate cause of plaintiff's alleged injuries. The plaintiff never contends that Takeda could have designed Dexilant differently before putting it into the stream of commerce, or that such a design is even feasible. She does not articulate how Dexilant may have been manufactured improperly. She never even identifies what the supposed defect in Dexilant is. Her allegations do not state plausible design or manufacturing defect claims against Takeda, for "[a] pleading that offers labels and conclusions[,] a formulaic recitation of the elements of a cause of action[,]" or "naked assertions devoid of further factual enhancement" will not suffice. *Iqbal,* 556 U.S. at 678 (quoting *Twombly,* 550 U.S. at 555, 557) (internal quotation marks omitted).

A bare allegation of a "defect" is no more than a legal conclusion. *See, e.g., Ojeda v. Louisville Ladder Inc.,* 2010 U.S. App. LEXIS 25534, *4 (11th Cir. Dec. 13, 2010) (plaintiff's statement that the ladder was defective because of its "improper design, shape, size, and configuration" was a legal conclusion); *United States v. Stephens,* 445 F.2d 192, 198 (3d Cir.

1971) (Aldisert, J., concurring) ("a naked claim of defective design" in a products liability case is a "[c]onclusory averment[] . . . and a statement of the ultimate legal principle" which requires "necessary specifics to support it."); *Rollins v. Wackenhut Servs.*, 802 F. Supp. 2d 111, 124 (D.D.C. 2011) ("Without further factual allegations about the supposedly defective nature of Abilify, the allegation that the drug is 'unreasonably dangerous' and hence defective is merely a legal conclusion."); *Bodley v. Foster Wheeler Energy Corp.*, 2011 U.S. Dist. LEXIS 45006, at *11-12 (D.V.I. Apr. 26, 2011) ("[T]here is consensus that when the plaintiff alleges that a product is defective in design, he or she has asserted a legal conclusion. . . . a plaintiffs bald assertion that a device is defective is insufficient to state a claim of products liability."); *Burks v. Abbott Labs.*, 2010 U.S. Dist. LEXIS 38616, at *9 (D. Minn. Apr. 20, 2010) (faulting pleader for, among other things, not alleging "any facts describing or identifying defendants' manufacturing specifications or standards" and, therefore, pleader failed "to allege facts describing how defendants' products deviated from such specifications or standards"); *Gomez v. Pfizer, Inc.* 675 F. Supp. 2d 1159, 1163 (S.D. Fla. 2009) (allegations that pharmaceutical products "were defectively designed and/or manufactured because [their] intended use resulted in a substantial and unreasonable likelihood of causing Stevens-Johnson syndrome, which rendered [them] unreasonably dangerous for [their] intended use," amounted to no more than "bare legal conclusions."); *Frey v. Novartis Pharms., Inc.*, 642 F. Supp. 2d 787, 790 (S.D. Ohio 2009) (same). In short, the plaintiff must plead supporting facts.

Accordingly, the Court dismisses Counts I, II and III, with prejudice, to the extent plaintiff attempts to plead design-defect and manufacturing-defect claims against the defendants.

D. Failure to Test.

Ball also alleges that Takeda failed to adequately test Dexilant before selling it. (Am. Compl. ¶¶ 22, 41.) "The Virginia Supreme Court has stated that a product may be 'unreasonably dangerous' in three ways, 'if it is defective in assembly or manufacture, unreasonably dangerous in design, or unaccompanied by adequate warnings concerning its hazardous properties.'" *Sykes v. Bayer Pharms. Corp.*, 548 F. Supp. 2d 208, 215 (E.D. Va. 2008) (quoting *Morgen Indus., Inc. v. Vaughan*, 471 S.E.2d 489, 492 (Va. 1996)). "By implication, any other type of product-liability claim cannot succeed." *Id.* (dismissing "failure to test" claim); *see also Torkie-Tork v. Wyeth*, 757 F. Supp. 2d 567, 572 (E.D. Va. 2010) (under Virginia law, drug manufacturer did not have a duty to conduct additional testing of its product beyond what was performed as part of the FDA approval process). No court has yet accepted a "failure to test" theory as a viable claim separate and apart from the three traditional product defect claims mentioned above. Any claim based on a "failure to test" theory, therefore, must be dismissed, with prejudice.

E. Negligence Per Se.

In Count 2, Ball contends that Takeda was negligent *per se* because it violated various statutes and regulations requiring pharmaceutical companies to warn consumers where evidence shows a drug "may be carcinogenic or mutagenic or that it impairs fertility." (Am. Compl. ¶¶ 36-39.) To establish negligence *per se*, the plaintiff must identify a specific statute or regulation violated by the defendant.

> A cause of action based on . . . a statutory violation is designated a negligence *per se* cause of action and requires a showing [1] that the tortfeasor had a duty of care to the plaintiff, [2] the standard of care for that duty was set by statute, [3] the tortfeasor engaged in acts that violated the standard of care set out in the statute, [4] the statute was enacted for public health and safety reasons, [5] the plaintiff was a member of the class protected by the statute, [6] the injury was of the sort intended to be covered by the statute, and [7] the violation of the statute was a proximate cause of the injury.

Steward v. Holland Family Props., LLC, 726 S.E.2d 251, 254 (Va. 2012) (citation omitted). The Amended Complaint fails to state a claim for negligence *per se* because it does not identify a particular statute or ordinance that Takeda allegedly violated.

Ball does cite statutes and regulations in her pleadings, but not in any enlightening form. In some instances, Ball cites various federal and state statutes and regulations having nothing at all to do with prescription drugs or with her injuries. For example, plaintiff inexplicably cites 21 U.S.C. § 20 ("Apples in Interstate Commerce") and 21 U.S.C. § 350 ("Vitamins and Minerals") as statutory bases for her negligence *per se* claim. Dexilant is neither an apple, nor vitamin nor mineral. She also relies on "Va. Code 54.1 at. el" [sic]. Title 54.1 of the Virginia Code, titled "Professions and Occupations," includes forty-four (44) separate chapters of statutes addressing a wide range of topics. Plaintiff never identifies the particular statute in Title 54.1 of the Virginia Code that Takeda allegedly violated.

With respect to statutes and regulations arguably bearing some connection to the pharmaceutical world, Ball again fails to particularize the specific provision Takeda allegedly violated. She refers to 21 C.F.R. pt. 201 (titled "Labeling") to support Count II, but Part 201 contains "comprehensive regulations – spanning an entire part of the Code of Federal Regulations, . . . with seven subparts and 70 separate sections – that set forth drug manufacturers' labeling obligations." *Wyeth v. Levine*, 555 U.S. 555, 608 (Alito, J., dissenting). In late April, this Court advised the plaintiff that if she intended to pursue a claim of negligence per se, "*she must identify in her amended complaint the specific law or regulation that she claims the defendants violated.*" (Dkt. no. 22 at 2 (emphasis added).) Despite this directive, Ball never identifies the particular regulation she believes Takeda violated. Even after the defendants pointed out this deficiency in their motion to dismiss, the plaintiff's opposition

brief still does not identify a single statute, regulation, or guideline that Takeda arguably violated. (*See* dkt. no. 32 at 9-10.) Rather, Ball only vaguely refers to unnamed "guidelines" and "requirements" applicable to prescription drugs.

This will not do. In a negligence *per se* claim, a plaintiff may not throw the kitchen sink of statutes and regulations at a defendant in the hope that someone will eventually figure out the particular statute or regulation the defendant violated. *See Twombly*, 550 U.S. at 558 ("[A] district court must retain power to insist upon some specificity in pleading before allowing a potentially massive factual controversy to proceed."). Indeed, "it is only by taking care to require allegations reach the level suggesting [the defendant's misconduct] that we can hope to avoid the potentially enormous expense of discovery in cases with no 'reasonably founded hope that the [discovery] process will reveal relevant evidence' to support [the plaintiff's] claim." *Twombly*, 550 U.S. at 559-60 (quoting *Dura Pharms., Inc. v. Broudo*, 544 U.S. 336, 347 (2005)). For whatever reason, plaintiff is unable to identify the specific statute or regulation the defendants arguably violated. Between *Takeda I* and *Takeda II*, plaintiff has filed five (5) motions to amend. In view of the multiple opportunities Ball has been afforded to correct her pleading deficiencies, the Court dismisses Count II, with prejudice.[6]

F. The VCPA.

In Count IV, Plaintiff alleges that Takeda violated the Virginia Consumer Protection Act because, knowing of Dexilant's risks, Tekada's warnings and labels falsely "stated that there was not any information on impaired fertility from the use of Dexilant." The VCPA, however, does

[6] "The granting of leave to file another amended complaint, when [plaintiff] was on notice of the deficiencies before filing the most recent amended complaint, would undermine the substantial interest of finality in litigation and unduly subject [Takeda] to the continued time and expense occasioned by [plaintiff's] pleading failures." *United States ex rel. Nathan v. Takeda Pharms. N. Am., Inc.*, 707 F.3d 451, 461 (4th Cir. 2013).

not apply to federally regulated products. The VCPA prohibits fraudulent practices in consumer transactions. *See* Va. Code § 59.1-200(A)(5), (A)(14). But it does not apply to all transactions:

> By its own terms, however, the VCPA does not apply to "[a]ny aspect of a consumer transaction which aspect is authorized under laws or regulations of this Commonwealth or the United States, or the formal advisory opinions of any regulatory body or official of this Commonwealth or the United States." Va. Code VA. CODE § 59.1-199(A).

Ali v. Allergan USA, Inc., 2012 U.S. Dist. LEXIS 121417, at *56-57 (E.D. Va. Aug. 23, 2012) (granting motion to dismiss VCPA claim against medical device manufacturer because "[r]epresentations about the LAP-BAND in marketing materials for the device are authorized and regulated by the FDA under federal law.").[7]

Dexilant is an FDA-approved drug whose warning labels are extensively regulated by federal law.

> [T]he drug's warning label "serves as the standard under which the FDA determines whether a product is safe and effective." 50 Fed. Reg. 7470 (1985). Labeling is "[t]he centerpiece of risk management," as it "communicates to health care practitioners the agency's [i.e., the FDA's] formal, authoritative conclusions regarding the conditions under which the product can be used safely and effectively." 71 Fed. Reg. 3934 (2006). The FDA has underscored the importance it places on drug labels by promulgating comprehensive regulations . . . that set forth drug manufacturers' labeling obligations.

Wyeth, 555 U.S. at 608 (Alito, J., dissenting).

Since federal law regulates the very matters the plaintiff says violate the VCPA, the plaintiff's VCPA claim fails as a matter of law. Count IV is dismissed with prejudice.

[7] "There is a strong argument that the scope of [consumer protection acts] was never meant to include FDA-approved drugs. The clear public policy behind these provisions is that consumer protection laws were meant to fill a gap by protecting consumers where product safety was not already closely monitored and regulated by the government." Victor E. Schwartz, et al., *"That's Unfair!" Says Who — The Government or the Litigant? Consumer Protection Claims Involving Regulated Conduct*, 47 Washburn L.J. 93, 119 (2007).

V. EXPERT WITNESS DESIGNATION

In some cases, the Court might allow a plaintiff to amend her complaint, but not here. Ball has had many opportunities to get the complaint right, but to no avail. Her lawyer has flagrantly violated Court Orders and the Rules of Civil Procedure, and, many months into the case, still cannot even allege the elements of her claims.

Now the plaintiff faces a fatal problem: she has no expert witness.

The Court entered a Pretrial Order on April 22, 2013, requiring Ball to (among other things) identify expert witnesses and provide disclosures by July 18, 2013. On July 18—the day designations were due—Ball moved for a one-month extension of time to identify her expert witness(es). (Dkt. no. 37.) Ball's reason for not identifying an expert is that she cannot afford one.[8]

Fed. R. Civ. P. 16(b)(4) provides that a pretrial "schedule may be modified only for good cause and with the judge's consent." "'Good cause' requires 'the party seeking relief [to] show that the deadlines cannot reasonably be met despite the party's diligence,' and whatever other factors are also considered, 'the good-cause standard will not be satisfied if the [district] court concludes that the party seeking relief (or that party's attorney) has not acted diligently in compliance with the schedule.'" *Cook v. Howard*, 484 F. App'x 805, 815 (4th Cir. Aug. 24, 2012) (quoting 6A Charles Alan Wright, et al., *Federal Practice and Procedure* Civ. 3d § 1522.2 (3d ed. 2010)).

[8] Ball's lawyer recites several hardships that led to his inability to advance the cost of an expert: her attorney hoped to get some money from settling another case, but the settlement went awry; he is in the process of ramping up his law practice after exiting the full-time practice of law between 2004 and 2011, and has simultaneously endured unspecified "family issues and business economic losses;" and he has searched for associate counsel who can fund the case, but the process is not yet complete.

Ball has not shown good cause for her failure to comply with the Court's expert disclosure deadline. Her difficulties simply reflect again her counsel's repeated failures to adhere to this Court's rules and overall lack of diligence in pursuing this action. Ball suffered her alleged injuries in September 2010. On September 28, 2012, Ball initially filed suit against Takeda alleging injuries arising out of her use of Dexilant. Thereafter, plaintiff's counsel refused to participate in the required Rule 26(f) conference, failed to propound initial disclosures in compliance with the Court's Initial Pretrial Order, failed to cooperate with defense counsel, and generally gummed up the case. As a sanction for the defendants' conduct, the Court dismissed the action without prejudice on March 15, 2013. See *Takeda I* (dkt. no. 39). That same day, Ball filed the current lawsuit alleging, once again, injuries resulting from the use of Dexilant. *See Takeda II.*

At the initial pretrial conference held on April 18, 2013, this Court inquired whether experts were prepared to offer opinions to support Ball's claims. Plaintiff's counsel responded:

> Yes. We are in conference with some of the experts in reference to bringing them on board, and things of that nature. So we're moving forward.

(April 18, 2013 Hr'g Tr. 14.) At a motion to dismiss hearing held on April 26, 2013, the Court specifically asked Ball's counsel, "Who is your expert?" (April 26, 2013 Hr'g Tr. 36.) Ball's counsel indicated that he had "talked to" an unnamed physician and paid him $2,000, but that the doctor had not provided a report.

The Court understands that products liability cases require not only skilled counsel but also a bankroll to fund trial preparation. Yet, while this case has been pending in one form or another for nearly a year, no sign of a plaintiff's expert looms on the horizon. The Court has repeatedly encouraged plaintiff's attorney to associate other counsel familiar with the demands of federal litigation, but to no avail. After filing the same lawsuit twice, and cognizant of the

need for an expert from day one, Ball remains—as she was before filing suit—without an expert witness. The Court also notes that Ball's counsel knew about all of the above problems (financial or otherwise) for many months, but remained silent about the issues until the very day expert disclosures were due. Such silence is the antithesis of diligence.

Deadlines exist in order to move litigation along. *See Dilmar Oil Co. v. Federated Mut. Ins. Co.*, 986 F. Supp. 959, 980 (D.S.C. 1997) ("A scheduling order is not a frivolous piece of paper, idly entered, which can be cavalierly disregarded by counsel without peril."). As the Seventh Circuit Court of Appeals has artfully summarized:

> We live in a world of deadlines. If we're late for the start of the game or the movie, or late for the departure of the plane or the train, things go forward without us. The practice of law is no exception. A good judge sets deadlines, and the judge has a right to assume that deadlines will be honored. The flow of cases through a busy district court is aided, not hindered, by adherence to deadlines.

Spears v. City of Indianapolis, 74 F.3d 153, 157 (7th Cir. 1996) (affirming district court's denial of plaintiff's request for an enlargement of time, stating that the district judge had "generously given [the plaintiff] more than enough time to get his act together, decided there would be no more extensions, and we cannot say he was wrong to put his foot down as he did.").

Considering the well-known need for expert testimony, and taking into account Ball's attorney's practice of putting his head in the sand concerning virtually all pretrial requirements, the Court finds that the plaintiff has not shown good cause to extend the deadline for identifying an expert witness. The Court DENIES plaintiff's motion to extend the time to name an expert. *See, e.g.*, *Campbell v. Donohue*, 2012 U.S. Dist. LEXIS 81147, at *3 (D.V.I. June 12, 2012) ("Counsel's statement regarding financial issues he may have with his client do not meet the burden of showing diligence or establishing good cause.").

As a consequence, the plaintiff faces trial on her surviving claims (negligent failure to warn and breach of the implied warranty) without any expert testimony. Of course, Ball has the burden to prove that Dexilant caused her alleged injuries. *E.g.*, *Alevromagiros v. Hechinger Co.*, 993 F.2d 417, 420 (4th Cir. 1993) (negligence claims based on a defective product under Virginia law). She must have expert testimony to meet her burden of proof. "[I]n a products liability action, proof of causation must ordinarily be supported by expert testimony because of the complexity of the causation facts." *McCauley v. Purdue Pharma L.P.*, 331 F. Supp. 2d 449, 464 (W.D. Va. 2004); *see also Rohrbough v. Wyeth Labs., Inc.*, 916 F.2d 970, 972 (4th Cir. 1990) (holding that essential element of causation in products liability action involving medical vaccine must be proved by expert testimony under West Virginia law); *Hartwell v. Danek Med., Inc.*, 47 F. Supp. 2d 703, 707 (W.D. Va. 1999) (holding same as to products liability case involving medical device under Virginia law).

A complete failure of proof concerning an essential element of a party's case necessarily renders all other facts immaterial. *Celotex*, 477 U.S. at 323. Since Ball cannot establish causation (or, for that matter, any other scientific aspect of her case), Takeda is entitled to judgment as a matter of law.

VI. OTHER PENDING MATTERS

Ball has filed motions to compel Takeda to respond to requests for admission (dkt. no. 43), to reconsider prior rulings of the Court (dkt. nos. 48 and 50), and to stay various proceedings and orders (dkt. no. 52). Her motions are rambling and unclear, and it is possible that she also seeks other relief. In any event, given the Court's rulings, all of the plaintiff's pending motions are DENIED.

Takeda has a pending request to award attorneys' fees arising from its successful motion to compel discovery responses. The request is denied.[9]

VII. CONCLUSION

For the reasons set forth above, the Court dismisses the entire case.

The Court will enter an appropriate order.

Date: August 8, 2013
Richmond, VA

/s/
John A. Gibney, Jr.
United States District Judge

[9] A party seeking fees must produce evidence "[i]n addition to the [plaintiff's] attorney's own affidavits" to establish the reasonableness of their hourly rate and number of hours worked on the case. *Robinson v. Equifax Info. Servs., LLC*, 560 F.3d 235, 244 (4th Cir. 2009); *see also Benson v. Vsim Patent Co. LLC*, 2013 U.S. Dist. LEXIS 63115 (E.D. Va. May 2, 2013). Takeda has not done so. Undoubtedly, Takeda recognized that collection of any amount is unlikely in this case, and wisely decided not to trouble other attorneys to review the fee request.